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No. 89-368

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

MERCK & CO., INC.,
Petitioner,

v.

BIOCRAFT LABORATORIES, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITIONER'S REPLY BRIEF

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STATEMENT PURSUANT TO RULE 28.1

The subsidiaries (except wholly-owned subsidiaries) and affiliates of Petitioner Merck & Co., Inc. are as previously identified on page ii of the Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit filed on September 5, 1989 in this case.

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PETITIONER'S REPLY BRIEF

PRELIMINARY STATEMENT

Petitioner Merck & Co., Inc. ("Merck") respectfully submits this Reply Brief (i) in further support of its belief that this Court should issue a Writ of Certiorari to review the Federal Circuit majority's conduct in this case, and (ii) to address several arguments first raised in the Opposition Brief filed by Respondent Biocraft Laboratories, Inc. ("Biocraft"). Merck maintains that there is an urgent need for this Court to exercise its supervisory authority over the Federal Circuit and address on the merits that Court's improper entry of *de novo* fact findings and reversal of trial court findings without proper regard to Rule 52(a) of the Federal Rules of Civil Procedure. And, the Federal Circuit majority's decision here

looms as dangerous precedent that threatens to serve as a disincentive which will discourage the pharmaceutical industry from engaging in the painstaking and costly research essential to the discovery of the medicines critical to human health.

It is respectfully submitted that Biocraft's arguments do not undercut the importance of this case or the need for this Court to consider the two questions presented by Merck's Petition.

ARGUMENT

I. THE FEDERAL CIRCUIT MAJORITY ENGAGED IN IMPROPER DE NOVO FACT FINDING AND IGNORED RULE 52(a)

In an effort to sustain a Federal Circuit majority opinion that does not even attempt to demonstrate that a single finding of fact entered by the District Court was "clearly erroneous"—indeed, the majority does not even mention Rule 52(a) of the Federal Rules of Civil Procedure—Biocraft asserts that "the clearly erroneous standard of Rule 52(a) is not an issue." (Bio. Opp. Br. at 2).[1] Like the majority, Biocraft attempts to side-step both Rule 52(a) and the critical and time-honored distinction between the proper functioning of federal trial and appellate courts. And, Biocraft—as it must in its effort to sustain the Federal Circuit majority's invasion of the exclusive fact finding province of the District Court—ignores the irreconcilable differences between the facts as found by the District Court and the majority's *de novo* findings upon which it grounded its reversal. (Pet. at 10-17).[2]

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[1] Biocraft's October 30, 1989 Brief in Opposition to Petition for Writ of Certiorari will be cited as "Bio. Opp. Br. at ——."

[2] Merck's September 5, 1989 Petition for a Writ of Certiorari will be cited as "Pet. at ——."

The critical factual findings of the District Court—and the dichotomous facts employed by the majority to reach an opposite conclusion—were set forth in some detail in the Petition, and Merck will not needlessly repeat those differences here. In sum, the District Court found that:

(i) the prior art '813 patent did *not* disclose the patented combination of amiloride and hydrochlorothiazide (App. B at 25a n.1);

(ii) the art was unpredictable and did not forecast the results produced by the '430 invention (App. B at 28a-29a, 33a); and

(iii) the prior art '813 patent contained no "hint" as to the proportions of amiloride and hydrochlorothiazide recited in Claim 3 of the '430 patent and contained in Merck's commercially successful product, Moduretic®—i.e., 5 mg of amiloride and 50 mg of hydrochlorothiazide (App. B at 30a).

The Federal Circuit majority did not determine any of those findings to be "clearly erroneous"—which it was required to do, pursuant to Rule 52(a), if it wished to set aside those findings. Indeed, the majority announced that it did "not quarrel with the factual findings of the district court." (App. A at 5a). Yet, it cannot be denied that, in truth, the majority expressly or impliedly set aside each of those crucial District Court fact findings and improperly made *de novo* findings of fact.

For example, the District Court findings above are irreconcilable with the Federal Circuit majority's factual assertions that:

(i) the amiloride/hydrochlorothiazide combination was not novel because it was disclosed in the prior art '813 patent (App. A at 5a);

(ii) the results achieved by the amiloride/hydrochlorothiazide combination were expected based upon the prior art '813 patent (App. A at 9a); and

(iii) the experimentation needed to arrive at the claimed dosages of 5 mg of amiloride and 50 mg of hydrochlorothiazide was nothing more than "routine" (App. A at 10a).

Clearly, under the guise of reviewing and reversing the District Court's conclusion of non-obviousness "as a matter of law" (App. A at 5a), in reality the Federal Circuit ignored Rule 52(a) and its proper, limited role as an appellate court.

II. THE FEDERAL CIRCUIT MAJORITY'S DE NOVO FINDINGS WERE ESSENTIAL TO ITS REVERSAL

Apparently recognizing the tenuous nature of its contention that "this is not a case where Rule 52(a) is implicated" (Bio. Opp. Br. at 13), Biocraft devotes a substantial portion of its opposition to an effort to convince this Court that the majority's conduct in entering *de novo* factual findings in this case need not be reviewed because those improper findings were not essential to the majority's reversal. Biocraft attempts to distract attention from the critical importance of the Federal Circuit's new findings by claiming that they were mere dicta. (*See* Bio. Opp. Br. at 17 n.5 and at 18 n.6). Nothing could be further from the truth.

Each of the *de novo* findings set forth in Point I, *supra*, was essential to the majority's rationale. Indeed, the concluding sentence of the majority's opinion on the merits unquestionably establishes that those findings were critical to the majority's decision:

> "Reached by means of *routine procedures*, and producing only *predictable results*, the *recited dosages* therefore do not distinguish the claims of the '430 patent from the amiloride/hydrochlorothiazide combination that the district court properly found was *disclosed* in the '813 patent." (App. A at 11a). (Emphasis added, citation omitted).

Without the improper *de novo* factual findings it entered on appeal, the majority could not have reached the conclusion to reverse. Thus, Merck respectfully submits that this case warrants the attention of this Court not only because an incorrect result has been reached, but because that result was reached only after the Federal Circuit—as it has in the past—overstepped the bounds of proper appellate review and invaded the District Court's province as the finder of fact.

III. THE FEDERAL CIRCUIT MAJORITY, AND BIOCRAFT IN OPPOSITION, IGNORED THE PRESUMPTION OF VALIDITY AND REVERSED THE BURDEN OF PROOF

Merck's '430 patent, like any other patent duly issued by the United States Patent and Trademark Office, was entitled to the statutory presumption of validity as set forth in 35 U.S.C. § 282:

> "A patent shall be presumed valid. . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity."

And, it is axiomatic that this statutory presumption of validity can be overcome only where the party challenging the patent (here, Biocraft) offers "clear and convincing" evidence of the facts necessary to a conclusion of invalidity. *Jones v. Hardy*, 727 F.2d 1524, 1528 (Fed. Cir. 1984).

Yet, here both the Federal Circuit majority, as well as Biocraft in its arguments before this Court, improperly have shifted the burden to Merck to prove that the '430 patent claimed invention was patentable. Thus, Biocraft argues its one-sided presentation of the evidence at length in an effort to sustain the majority's *de novo* findings and faulty analysis. (*See, e.g.*, Bio. Opp. Br. at 16-24). For

example, Biocraft argues at length that "*the overwhelming evidence established that the claimed combination did not in fact achieve these results* [i.e., unexpected amounts of sodium excretion]." (Bio. Opp. Br. at 17). (Emphasis in original). But, what Biocraft—and the Federal Circuit majority before it—ignores is that Merck was under no obligation to prove unexpected results at trial. Rather, the burden was on Biocraft to prove to the District Court—by clear and convincing evidence—that no unexpected results were achieved. Biocraft failed to convince the District Court, and the District Court made no finding that the '430 patented combination did not achieve unexpected results. Indeed, while the District Court did not enter an express finding that unexpected results were achieved by the specific combination employed in Merck's Moduretic®, fairly read the District Court's opinion reveals that it indeed found that the amiloride/hydrochlorothiazide combination caused increased sodium excretion which could not have been forecast based upon the prior art.[3]

Biocraft's Opposition is replete with arguments as to what was established by the trial evidence. In essence, Biocraft argues that the evidence supported the majority's view of the facts. Obviously, Merck—and the District Court—are of a different opinion as to what was proven by the trial evidence. But, that is not the issue. An appellate court is not free to substitute its view of the evidence for that of the District Court. *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 573 (1985). And, even where the trial evidence could be construed to

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[3] Biocraft cannot point to a single District Court finding to support the naked assertion that the District Court "found" that the patented combination did not cause more sodium excretion than would have been expected. (Bio. Opp. Br. at 4). To the contrary, the evidence introduced at trial did lead the District Court to enter the factual findings set forth in detail in Merck's Petition at 11 n.5.

support either party's factual assertions, the District Court's choice between the conflicting views of the evidence must be sustained because it cannot be regarded as clearly erroneous. *Id.*, 470 U.S. at 573-75.

Moreover, arguments as to what the trial evidence established are inappropriate at this stage of the proceedings. The question is whether the majority was entitled to ignore Rule 52(a) and contravene the precedents of this Court by disregarding key factual findings of the District Court and making *de novo* findings. Merck will refrain from arguing the evidence, hoping to have the opportunity to make those arguments in its brief on the merits.

IV. THE MAJORITY INVALIDATED MERCK'S VALUABLE '430 PATENT EVEN THOUGH THE INVENTION WAS MERELY OBVIOUS TO TRY, ESTABLISHING A PRECEDENT WHICH WILL UNDERCUT THE INCENTIVES FOR PAINSTAKING PHARMACEUTICAL RESEARCH

In its Petition, Merck articulated how the Federal Circuit majority's opinion is a dangerous precedent, undermining the validity of patents directed to pharmaceutical compositions and potentially discouraging the costly research required to discover new and beneficial medicines. (Pet. at 22-27). In particular, the majority held obvious Merck's commercially successful diuretic composition, Moduretic®, even though that composition was but one of over 1200 combinations that were merely "obvious to try." Biocraft's arguments in opposition do not detract from the serious disincentives created by the majority's opinion.

Biocraft argues that the Federal Circuit overall has had a positive impact on the value of patents by creating a climate more favorable to sustaining their validity. (Bio. Opp. Br. at 11-12). That, however, is entirely beside the point. The Federal Circuit's function is not and

should not be either pro- or anti-patent; it should be to decide cases correctly through the proper exercise of its role as an appellate court. *See Graver Mfg. Co. v. Linde Co.*, 336 U.S. 271, 279 (1949), *aff'd on rehearing*, 339 U.S. 605, *reh'g denied*, 340 U.S. 845 (1950) (same deference is due to trial court findings which overturn claims as to findings which sustain them).

Biocraft also argues that the Federal Circuit has upheld patents "in the pharmaceutically related areas", citing two Federal Circuit decisions. (Bio. Opp. Br. at 12). Not only is that argument meritless, but the cases relied upon by Biocraft do not even deal with the unique and specialized field of pharmaceutical chemical compositions for human consumption.[4]

Because of the potential industry-wide significance of this case, this Court should grant Certiorari.

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[4] Biocraft also repeatedly urges that Merck received two patents (the prior art '813 patent and the '430 patent-in-suit) for the same invention. (Bio. Opp. Br. at 3, 12-13, 25). That argument is incorrect and irrelevant here, having formed no part of the Federal Circuit majority's opinion.

CONCLUSION

Merck respectfully submits that each question presented in its Petition has significance that reaches beyond both Merck and Biocraft and deserves this Court's consideration. The proper role of the Federal Circuit in reviewing district court fact findings which underlie the obviousness issue has never been addressed on the merits by this Court and requires clarification. Moreover, the potential negative impact of the majority's decision on the pharmaceutical industry is a significant question of far-reaching concern.

Accordingly, it is respectfully urged that Merck's Petition should be granted and a Writ of Certiorari should issue.

Respectfully submitted,

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